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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,975	03/16/2004	Robert S. Biscup	MEDR 2 00001	2554
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Fay Sharpe LLP 1228 Euclid Avenue, 5th Floor The Halle Building Cleveland, OH 44115				
EXAMINER				
RAMANA, ANURADHA				
ART UNIT		PAPER NUMBER		
3775				
MAIL DATE		DELIVERY MODE		
02/03/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/801,975

Applicant(s)

BISCUP ET AL.

Examiner

Anu Ramana

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,12,14-37,39,53,78 and 80 is/are pending in the application.
- 4a) Of the above claim(s) 9-11,13,38,40-52,77,79 and 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8,12,14-37,39,53,78 and 80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/7/08; 5/22/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

It is noted that claims 46 and 47 are withdrawn from consideration since they are directed to nonelected species. Correct status identifiers must be used in the response to this office action.

Claims 78 and 80 are objected to due to minor informalities. The recited phrase "same and form" should be "shape and form" to correct a minor typographical error.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation "majority of said substantially spherical or ellipsoidal body is non-expandable" is deemed to be new matter because this recitation implies that a portion of the substantially spherical or ellipsoidal body could be expandable, which is not supported by Applicant's disclosure, as originally filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-8, 12, 15-22, 24-37, 39, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (US 5,571,189).

Kuslich discloses a prosthetic implant including: a substantially spherical bag 40 made of a material impregnated with a biologically active material such as ground up bone graft, i.e., unexpandable component; and an inflatable band or "expandable component" or "stabilizer" 42 having a disc shape (Figs. 9 and 13, col. 6, lines 57-67, cols. 7-9 and col. 10, lines 1-9).

Using an alternate interpretation, claims 78 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (US 5,571,189).

Kuslich discloses a prosthetic implant including: a band 42 of molded plastic or "non-expandable component" and a fabric bag or "expandable component" (col. 7, lines 8-52, col. 9, lines 66-67 and col. 10, lines 1-16).

It is noted that band 42 "substantially retains" its shape and form since it is formed of molded plastic, a material stiffer than the bag fabric.

Kuslich also discloses the use of hydroxyapatite to fill the implant (col. 12, lines 16-22). It is noted that materials such as hydroxyapatite expand as they harden.

The method steps of claims 78 and 80 are inherently performed when the Kuslich implant is filled with hydroxyapatite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (US 5,571,189).

Regarding claim 14, although Kuslich does not disclose the relative dimensions of the band with respect to the balloon, it has been held that, where the only difference between the prior art and the claims is the recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than a prior art device, the claimed device is not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F. 2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding claim 23, although Kuslich does not specifically disclose the expandable component to have a tapered edge, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the Kuslich band with a shape having a tapered edge, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a stabilizer element. In re Dailey and Eilers, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments filed November 11, 2008 have been carefully considered by the Examiner.

The examiner is withdrawing the objection to the oath/declaration based on Applicant's comments.

Applicant's arguments with respect to the double patenting rejections are persuasive. Accordingly, the double patenting rejections have been withdrawn.

Applicant's arguments with respect to the rejections under 35 USC 102(b) over Kuslich are not persuasive for the following reasons.

Kuslich clearly discloses implant 40 to have an unexpandable component or portion, namely, bone graft and an expandable component 42. In an embodiment, band 42 is disclosed to be formed of multiple layers of fabric which forms the bag (col. 10, lines 7-9).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached on Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

February 1, 2009

/Anu Ramana/

Primary Examiner, Art Unit 3775